510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company:.....3M ESPE AG
Street:.....ESPE Platz
ZIP-Code, City:.....D-82229 Seefeld
Federal State: .....Bavaria
Country: .....Germany
Establishment Registration Number 9611385
Official Correspondent: .....Dr. Andreas Petermann,
.....Manager Regulatory Affairs
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Date:.....April 20, 2007

Name of Device

Proprietary Name:.....Uno
Classification Name:.....Resin tooth bonding agent
Common Name: .....Dental Adhesive

Predicate Devices

Adper Prompt L-Pop by 3M ESPE.....K060684
Prompt L-Pop by 3M ESPE.....K001494
Hermes Bond 2 by 3M ESPE.....K043043
RelyX Unicem by 3M ESPE.....K020256
ESPE Sil by 3M ESPE.....K913965
Sinfony by 3M ESPE.....K992645

Description for the Premarket Notification

Uno is classified Resin Tooth Bonding Agent (21 C.F.R. § 872.3200) because it is a device intended to be painted on the interior of a prepared cavity of a tooth to improve retention of restorative materials (compomer and composite restorative material).

Like Adper Prompt L-Pop, 3M ESPE's well-known and well-established resin bonding agent, Uno offers the advantages of a simplified bonding procedure, eliminating the need for a separate etching step. Thus it reduces both possible errors during application and post-operative sensitivity. Additionally, it saves the dentist valuable chair time. Being based on methacrylate chemistry itself, Uno is well suited for bonding methacrylate based composites to dentin and enamel.

Uno is also indicated to seal sensitive root surfaces as is Adper Prompt L-Pop.

Furthermore, Uno is suited to bond orthodontic appliances to teeth for orthodontic treatment as is Prompt L-Pop.

Like Adper Prompt L-Pop, Uno will be available in single dose applicators and in a vial version.

To provide evidence for safety biocompatibility testing was carried out. The results show that Uno is a safe device.

The comparison for chemistry, performance data and indications for use shows that Uno is substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for Uno are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2007

Dr. Desi W. Soegiarto
Regulatory Affairs Specialist
3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria
GERMANY D-82229

Re: K071131
Trade/Device Name: Uno
Regulation Number: 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: June 27, 2007
Received: July 9, 2007

Dear Dr. Soegiarto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Uno

Indications For Use:

- All classes of fillings (according to Black) with light-curing composite or compomer
- Cementation of indirect restorations made of composite or compomer, ceramic, and metal using RelyX™ ARC, manufactured by 3M ESPE
- Core build-ups made of light-curing composite
- Root surface desensitization
- Repair of composite or compomer fillings
- Repair of restorations veneered with composite or ceramic
- Bonding orthodontic appliances to teeth for orthodontic treatment

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K071131